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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,949	12/09/2003	Sydney M. Finegold	111828-00113	8848

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EXAMINER	
WARE, DEBORAH K	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/729,949	FINEGOLD, SYDNEY M.	
	Examiner	Art Unit	
	Deborah K. Ware	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 9-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 9-17* is/are rejected.

7)☒ Claim(s) *1-3 and 9-17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 10-12-05,
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-3 and 9-17 are presented for reconsideration on the merits.

Response to Amendment

The amendment filed March 10, 2006, has been received and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

Claims 1-3 and 9-17 are objected to because in each of claims 13 and 14 "antimicrobial agent" should be a --antibacterial agent—so that terms will be consistent. Also claim 15 should depend from claim 14 and not claim 13 and "said microorganism" should read as –said abnormal microorganism--, also for consistency purposes. Also claim 16 should be changed to depend from claim 14 and the term "microorganism" at line 2 in claim 16 should be changed to –said abnormal microorganism--. Further, claims 1-3 and 9-16 are objected to for the misspelling of "biopolar" which should be –bipolar--.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 9-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *treating* a disease associated with an abnormal gastrointestinal flora selected from juvenile rheumatoid arthritis, multiple-

sclerosis, automimmune disease, Attention Deficit Disorder, depression, bipolar disorder, Alzheimer's disease, Parkinson's Disease, Whipple's Disease, Tourette's Syndrome, Asperger's syndrome, Pervasive Development Disorder, early onset autism, regressive autism, Rhett's Syndrome, schizophrenia, obsessive-compulsive disorder, and chronic fatigue syndrome, does not reasonably provide enablement for *preventing* these diseases or disorders.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice and carry out the invention commensurate in scope with these claims. Before Applicants' claims were much broader and did not require these specific diseases or disorders per se for prevention thereof, however, now with newly provided amendments the claims are newly limited to these disorders of which are assoicated with the presence of abnormal gastrointestinal flora in the gut of a subject in need of treatment and prevention thereof.

However, the scope of the claimed method can not be carried out as newly claimed since it is difficult to ascertain by one of ordinary skill in the art as to whether any of these disorders are prevented. Applicants specification does not enable one of skill in the art to prevent these disorders and diseases and have shown no results that they have obtained to demonstration preventing these disorders and diseases. There would be a high degree of unpredictability in the art for one of skill to be able to determine the prevention of any of these diseases and disorders. The amount of experimentation required to ascertain whether or not the claims can be carried out commensurate in scope with the presently claimed method would be insurmountable

and an undue burden on one of skill in the art. Thus, the claims should be limited to the scope for which the disclosure is enabled for and as recognized by the prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 and 9-17 remain rejected under 35 U.S.C. 103(a) as obvious over Perry (U.S. Patent No. 6,203,797) in view of for reasons of record and as set forth below.

Claims are newly drawn to method of treating or preventing a selected disease associated with abnormal flora in the gut with probiotic agent, wherein the disease can be limited to Chronic Fatigue Syndrome.

Perry teach treating or preventing disease associated with abnormal flora in the gut with probiotic agent which includes fatigue (i.e. Chronic Fatigue Syndrome), note column 7, lines 10-11. Clostridium difficile is disclosed to be the harmful bacteria, see column 5, lines 30-35 and line 40. Bifidobacterium is one of the organisms disclosed but the reference discloses many others.

The claims differ from Perry in that Chronic Fatigue Syndrome is not specifically disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to administer a treatment method and composition as disclosed by Perry because he recognized that various forms of fatigue are treatable with a similar treatment process. One of skill in the art upon a reading of Perry would have been motivated to treat Chronic Fatigue Syndrome using the treatment process and composition of Perry with the expectation of successful results. The same abnormal flora is disclosed, Clostridium difficile and the toxins produced therefrom, note column 5, line 40. Further, Perry discloses administering the probiotic after an antibacterial agent (i.e. bromelain), see the abstract. Bromelain is a natural enzyme from pineapple which has antibacterial properties because it facilitates lysis of cell walls of bacteria. The probiotic agent is selected from Lactobacillus and Bifidobacterium. Also the composition can be in tablet form, note column 3, line 29. Furthermore, the probiotic

microorganisms can produce bacterocins too, note column 7, lines 40-41. To select for other antibacterial agents is clearly within the purview of one of skill in the art. In the absence of persuasive evidence to the contrary the claims are prima facie obvious over the cited prior art.

Response to Arguments

Applicant's arguments filed March 10, 2006, have been fully considered but they are not persuasive. The crux of Applicants' argument is that Perry fails to teach the scope of the diseases as newly recited in claim 1, however, as discussed above Perry does teach or at least suggests Chronic Fatigue Syndrome by his teaching of treating fatigue of which Chronic Fatigue Syndrome is so coined. A person so fatigued and treated as disclosed by Perry would have been expected to also be treated for Chronic Fatigue Syndrome because Perry treats fatigue per se. To the contrary of Applicants' arguments, one of skill in the art would have been motivated and would have further expected successful results The claims for these reasons remain prima facie obvious over Perry.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 and 9-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 10/297,131. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are made obvious from the copending claims since both administer to a patient a probiotic. One of skill in the art would have been motivated and expected successful results by the copending claims to provide for the method of treating as claimed in the instant case.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed March 10, 2006, have been fully considered but they are not persuasive. It is noted that Applicants will consider filing a terminal disclaimer later, and they have presented no further arguments.

Thus, the claims are properly rejected.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deborah K. Ware
May 27, 2006

DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT ~~128~~ 1651